

**United States Department of Agriculture
Biotechnology Risk Assessment Grants Program
Annual Project Director's Meeting**



USDA APHIS-BRS
Riverdale, Maryland
May 23, 2017



United States Department of Agriculture
National Institute of Food and Agriculture



United States
Department of
Agriculture

National
Institute of Food
and Agriculture

USDA Biotechnology Risk Assessment Grants Program 2017 Annual Project Director's Meeting

Welcome to the 2017 Annual Project Director's (PD) Meeting for the USDA Biotechnology Risk Assessment Grants (BRAG) Program. This year's meeting includes awardees of proposals submitted in fiscal years 2013, 2014, 2015, and 2016.

Authority for the BRAG program is contained in section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (i.e., 1990 Farm Bill) and amended in section 7210 of the Farm Security and Rural Investment Act of 2002 (i.e., 2002 Farm Bill). In the Food, Conservation, and Energy Act of 2008 (i.e., 2008 Farm Bill), the authority was not repealed, so the BRAG program continued its role in supporting risk assessment research related to biotechnology. In accordance with the legislative authority in the 2002 Farm Bill, the BRAG program supports research designed to identify and develop appropriate management practices to minimize physical and biological risks associated with genetically engineered (GE) animals, plants, and microorganisms. The USDA's National Institute of Food and Agriculture (NIFA) and Agricultural Research Service (ARS) jointly administer the BRAG program. The U.S. Forest Service commits additional funding.

The main purpose of the BRAG program is to support the generation of new information that will assist Federal regulatory agencies in making science-based decisions about the effects of introducing into the environment GE organisms, including plants, microorganisms (including fungi, bacteria, and viruses), arthropods, fish, birds, mammals and other animals excluding humans. Investigations of effects on both managed and natural environments are relevant. The BRAG program accomplishes its purpose by providing Federal regulatory agencies with scientific information relevant to regulatory issues.

The overall goal of the PD Meetings is to improve post-award management of competitive grants administered by USDA and encourage an open dialogue between researchers and federal regulatory agencies on emerging topics related to biotechnology research. In turn, this will assist Program Staff in identifying success stories resulting from USDA-

sponsored research in the BRAG program and facilitate the reporting of important impacts resulting from the most successful research through communications with Congress, the Secretary and Undersecretary of Agriculture, USDA administrators, federal regulators, the scientific community, commodity groups and other stakeholders, and the general public. It is critical to identify and highlight these impacts in order to maintain funding in USDA's biotechnology risk assessment program areas, as well as to continue the recent trend of increased Congressional budget appropriations to USDA competitive grant programs. Conducting annual meetings for awardees is just one of several approaches being implemented by USDA to improve post-award management.

A second purpose of this meeting is to foster communication among awardees in this program and federal regulators, such as USDA Animal and Plant Health Inspection Service-Biotechnology Regulatory Service, U.S. Environmental Protection Agency, and the U.S. Food and Drug Administration, which have scientific interests in risk assessment research. It is anticipated that the sharing of information and the ensuing dialogue that will occur in this informal setting will allow all awardees to benefit from the experiences of their colleagues and yield greater opportunity for successful completion of their BRAG awards. In addition, it is expected that improved communication among BRAG awardees will result in better sharing of limited resources and the development of new fruitful collaborations.

We look forward to a highly successful and productive meeting, and we eagerly anticipate continued progress on your BRAG awards.

Respectfully,

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**United States Department of Agriculture (USDA)
Biotechnology Risk Assessment Grants (BRAG) Program
Project Director's Meeting**

May 23, 2017

USDA-APHIS-BRS Headquarters
Oklahoma Memorial Conference Center
4700 River Road
Riverdale, MD 20737

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|-------------------------|---|
| 8:30 - 9:00 AM | Arrival and Poster Setup |
| 9:00 - 9:05 AM | Welcome
Ibrahim Shaqir, Associate Deputy Administrator – USDA-APHIS |
| 9:05 - 9:25 AM | BRAG Program Overview
Shing Kwok/Lakshmi Matukumalli – USDA-NIFA |
| 9:25 - 9:40 AM | Environmental Assessment of GE Animals at U.S. HHS-FDA
Evgenij Evdokimov – U.S. FDA |
| 9:40 - 9:55 AM | EPA regulation of plant-incorporated protectants and microbial pest control agents
Milutin Djurickovic – U.S. EPA |
| 9:55 - 10:10 AM | Biotechnology Regulations and Research Priorities
Sally McCammon – USDA-APHIS-BRS |
| 10:10 - 10:30 AM | Break |
| 10:30 - 10:50 AM | Extended Pest Migration in Bt versus Non-Transgenic Crops
Impacts on Risk Assessment and Bt Resistance Dissemination
Juan Jurat-Fuentes – University of Tennessee, Knoxville |
| 10:50 - 11:10 AM | Risk Assessment for Plant Incorporated Insecticidal Products on
Non-Target Aquatic Invertebrates
William Lamp – University of Maryland, College Park |
| 11:10 - 11:30 AM | Assessing Phenotypic Variations in Soybean seed protein and oil
traits using GFP as a reporter in both mutagenesis and
transgenomic approaches
Monica Schmidt – University of Arizona, Tucson |
| 11:30 - 1:00 PM | Lunch - On Your Own |

- 1:00 - 1:20 PM Consistent Risk Assessment of Genetically Modified Microorganisms in the Field**
Raymond St. Leger – University of Maryland, College Park
- 1:20 - 1:40 PM Impact of transgenic Bt crops on *Helicoverpa zea* ecology and subsequent resistance risk**
Dominic Reisig – North Carolina State University
- 1:40 - 2:00 PM Genetic containment in livestock via CRISPR-mediated gene knock-in**
Alison Van Eenennaam – University of California, Davis
- 2:00 - 3:00 PM Discussion**
- 3:00 - 3:15 PM Break**
- 3:15 - 4:00 PM Poster Session #1 – Odd Numbered**
- 4:00 - 4:45 PM Poster Session #2 – Even Numbered**

2017 BRAG PD Meeting Poster List

#	Award Year	Name	Institution	Presentation Titles
1	2016	Burke, J.	University of Georgia	Short-term experiments as predictors of long-term patterns of gene introgression in crop-wild hybrids
2	2016	Busov, V.	Michigan Technological University	Utility of STERILE APETALA (SAP) for development of a sterility transgenic containment technology in poplar
3	2016	Egan, S.	Rice University	Monitoring the Dispersal of Genetically Engineered Organisms and Their Byproducts Using Light Transmission Spectroscopy II
4	2016	Fritz, M.	University of Maryland, College Park	Improving Bt Risk Assessment and Management by Genomic Monitoring
5	2016	Hunt, T.	University of Nebraska, Lincoln	Evaluating the Efficacy of Insect Resistance Management Plans for Delaying the onset of Bacillus Thuringiensis Toxin Resistance in Western Bean Cutworm Populations
6	2016	Lee, J.	Old Dominion University	Designer Algae Biotechnology Risk Assessment
7	2016	Liu, W.	University of Tennessee	Bioconfinement of Camelina sativa as a sustainable oilseed crop via cleistogamy
8	2016	Scott, M.	North Carolina State University	Development and evaluation of safeguards for conditional suppressive gene drives for spotted wing Drosophila and the New World screwworm
9	2016	Wang, K.	Iowa State University	A Data-Driven Approach to CRISPR Design for Reduced Off-Target Activity in Plant Genome Editing

10	2015	Auer, C.	University of Connecticut	Improving ecological risk assessments for <i>Camelina sativa</i> through research on pollen dispersal, gene flow and weed populations
11	2015	Handler, A.	USDA-ARS, Gainesville, FL	Assessment and mitigation of genetic breakdown of transgenic conditional lethality systems in insect pest species
12	2015	Morrell, P.	University of Minnesota	Comparison of mutation rates in soybean following transformation, mutagenesis, tissue culture and conventional breeding.
13	2015	Sword, G.	Texas A&M University	Nutritionally-mediated variation in <i>Helicoverpa zea</i> susceptibility to Bt transgenic crops
14	2015	Wong, T.	University of Maryland, Baltimore County	Developing An Inducible Sterilization Technology To Bio-Contain Transgenically Engineered Tilapia
15	2014	Carrière, Y.	University of Arizona	Resistance Risk Assessment for Seed Mixture Refuges with Pyramided Bt Corn
16	2014	Dunham, R.	Auburn University	Targeted Gene Knockout of Reproductive Genes of Catfish with Hormone Therapy to Restore Fertility
17	2014	Strauss, S.	Oregon State University	Efficacy and ecological impacts of transgenic containment technologies in poplar
18	2013	Brunet, J.	USDA-ARS, Madison, WI	Linking pollinator behavior to gene flow to reduce gene flow risk over the landscape
19	2013	Douches, D.	Michigan State University	Assessing The Impact Of Gene Replacement And Genetic Modification Methods In A Crop Species At The Whole Genome Level
20	2013	Gu, X.	South Dakota State University	Silencing of naturally occurring genes controlling seed dormancy to reduce fitness of transgene-contaminated weedy rice

Biotechnology Risk Assessment Grant Program Projects

Award Year	Investigator	Institution	Title	Project Report Link
2016	Burke, J.	University of Georgia	Short-term experiments as predictors of long-term patterns of gene introgression in crop-wild hybrids	Brief Full
2016	Busov, V.	Michigan Technological University	Utility of STERILE APETALA (SAP) for development of a sterility transgenic containment technology in poplar	Brief Full
2016	Egan, S.	Rice University	Monitoring the Dispersal of Genetically Engineered Organisms and Their Byproducts Using Light Transmission Spectroscopy II	Brief Full
2016	Fritz, M.	University of Maryland, College Park	Improving Bt Risk Assessment and Management by Genomic Monitoring	Brief Full
2016	Hunt, T.	University of Nebraska, Lincoln	Evaluating the Efficacy of Insect Resistance Management Plans for Delaying the onset of Bacillus Thuringiensis Toxin Resistance in Western Bean Cutworm Populations	Brief Full
2016	Lee, J.	Old Dominion University	Designer Algae Biotechnology Risk Assessment	Brief Full
2016	Liu, W.	University of Tennessee	Bioconfinement of Camelina sativa as a sustainable oilseed crop via cleistogamy	Brief Full
2016	Scott, M.	North Carolina State University	Development and evaluation of safeguards for conditional suppressive gene drives for spotted wing Drosophila and the New World screwworm	Brief Full

2016	Wang, K.	Iowa State University	A Data-Driven Approach to CRISPR Design for Reduced Off-Target Activity in Plant Genome Editing	Brief Full
2015	Auer, C.	University of Connecticut	Improving ecological risk assessments for <i>Camelina sativa</i> through research on pollen dispersal, gene flow and weed populations	Brief Full
2015	Handler, A.	USDA-ARS, Gainesville, FL	Assessment and mitigation of genetic breakdown of transgenic conditional lethality systems in insect pest species	Brief Full
2015	Morrell, P.	University of Minnesota	Comparison of mutation rates in soybean following transformation, mutagenesis, tissue culture and conventional breeding.	Brief Full
2015	St. Leger, R.	University of Maryland, College Park	Consistent Risk Assessment of Genetically Modified microorganisms in the Field	Brief Full
2015	Sword, G.	Texas A&M University	Nutritionally-mediated variation in <i>Helicoverpa zea</i> susceptibility to Bt transgenic crops	Brief Full
2015	Van Eenennaam, A.	University of California, Davis	Genetic containment in livestock via CRISPR-mediated gene knock-in	Brief Full
2015	Wong, T.	University of Maryland, Baltimore County	Developing An Inducible Sterilization Technology To Bio-Contain Transgenically Engineered Tilapia	Brief Full
2014	Carrère, Y.	University of Arizona	Resistance Risk Assessment for Seed Mixture Refuges with Pyramided Bt Corn	Brief Full
2014	Dunham, R.	Auburn University	Targeted Gene Knockout of Reproductive Genes of Catfish with Hormone Therapy to Restore Fertility	Brief Full

2014	Jurat-Fuentes, J.	University of Tennessee	Extended pest migration in Bt versus non-transgenic crops: impacts on risk assessment and Bt resistance dissemination	Brief Full
2014	Lamp, W.	University of Maryland, College Park	Risk Assessment for Plant Incorporated Insecticidal Products on Non Target Aquatic Invertebrates	Brief Full
2014	Reisig, D.	North Carolina State University	Impact of transgenic Bt crops on Helicoverpa zea ecology and subsequent resistance risk	Brief Full
2014	Schmidt, M.	University of Arizona	Assessing Phenotypic Variations in Soybean seed protein and oil traits using GFP as a reporter in both mutagenesis and transgenomic approach	Brief Full
2014	Strauss, S.	Oregon State University	Efficacy and ecological impacts of transgenic containment technologies in poplar	Brief Full
2013	Brunet, J.	USDA-ARS, Madison, WI	Linking pollinator behavior to gene flow to reduce gene flow risk over the landscape	Brief Full
2013	Douches, D.	Michigan State University	Assessing The Impact Of Gene Replacement And Genetic Modification Methods In A Crop Species At The Whole Genome Level	Brief Full
2013	Gu, X.	South Dakota State University	Silencing of naturally occurring genes controlling seed dormancy to reduce fitness of transgene-contaminated weedy rice	Brief Full

QUESTIONS FOR DISCUSSION

1. If intentional DNA alterations are to be regulated as New Animal Drugs, how will developers differentiate between
 - intended changes and associated unintentional changes (perhaps due to off target effects)
 - de novo naturally-occurring changes that occur every generation and sequencing errors (that arise as a result of the accuracy of sequencing methodology?)
2. What is the current federal regulatory guideline on GE blue-green algae-based biotechnology and risk assessments?
3. Are any new regulations being drafted for the release of GMOs carrying Cas9-based gene drive systems?
4. What support do agencies have to help regulate American transgenic technologies with application in countries with less regulatory expertise and capacity?
5. What is the status of IRM mandates for RNAi crops?
6. How will transgenic plants containing CRISPR reagents be regulated? Any specific regulation for potential gene-drive transgenic plants?
7. (Question from regulator to scientific community): Is the scientific community looking at the impact of sustainable agricultural methods (i.e. row crop rotations such as bt corn, non bt corn (resistant varieties, soy, wheat, alfalfa) with block refuges?
8. (Question from regulator to scientific community): Is anyone looking at these types of sustainable row cropping systems using resistant varieties coupled with releases of non-resistant pest species? It is understood that this could be controversial due to the releases of pest species, but perhaps limiting resistance alleles at a discrete level could bring long term benefits for row cropping systems.

APPENDIX: Appropriate Acknowledgment of Your USDA Award

The Biotechnology Risk Assessment Grant (BRAG) program plays an essential role in fulfilling the mission of the United States Department of Agriculture (USDA). Proper acknowledgment of your USDA BRAG funding in published manuscripts, presentations, press releases, and other communications is critical for the success of our USDA's programs. This includes proper acknowledgment of the Program and agencies, as well as that of the Department and grant number (Please note that the '####-#####-#####' below refers to your award number and not your proposal number).

We expect you to use the following language to acknowledge USDA support, as appropriate:

'This project was supported by Biotechnology Risk Assessment Grant Program competitive grant no. ####-#####-##### from the U.S. Department of Agriculture.'

We also expect that you will use our agency's identifier in all of your slide and poster presentations resulting from your BRAG award. The identifier is sent to you twice annually for at least 2 years after the termination date of your grant.



**United States
Department of
Agriculture**

Please alert us of significant findings, publications, news releases, and other media coverage of your work. With your permission, we may highlight your project in a national impact story or news release. If your research is featured on the cover of a scientific journal, we can showcase the cover as well.

Examples of these publications can be found at:

www.nifa.usda.gov/newsroom/newsroom.html.